

TESTIMONY BEFORE DIETARY SUPPLEMENT STAKEHOLDER MEETING
FOOD AND DRUG ADMINISTRATION

July 20, 1999
Oakland California

The proliferation of so-called nutritional supplements and other products falling under the umbrella of the DSHEA is overwhelming and, at the present time, it is almost impossible for the average consumer to be accurately informed about these products. With the steady increase of these products on the market, many have seemingly crossed the line between allowable claims and those which are specifically precluded. Few of these products have been subjected to thorough clinical investigation and our concern is that many of them are making unsubstantiated claims, not necessarily on their labels, but in their advertising and marketing literature.

Take, for example, the case of the supplements MSM and GH3 (Gero-Vita). In a best-selling book on MSM, the authors recommend its use for the treatment of (in alphabetical order), allergies, asthma, emphysema, fibromyalgia, heartburn, lupus, osteoarthritis, rheumatoid arthritis, sinusitis and temporomandibular joint disease. GH3, which is the subject of massive direct mail appeals, is said to increase circulation, relieve joint pain, decrease blood pressure, improve diabetes and make age spots disappear. Unfortunately, the only evidence presented to back up these incredible claims is anecdotal and completely unsupported by any actual controlled clinical investigation.

While most manufacturers abide by FDA's requirements for what the labels must say (name of substance, amount of the specific nutrient, part of the plant used, serving size and a disclaimer that the FDA has not evaluated the efficacy or safety of the product), the advertising material that accompanies these supplements completely violates the spirit and intent of the existing laws against making specific health claims for their use. While the truth of advertising, is a matter for the Federal Trade Commission to address, we believe that neither the FTC nor the FDA is doing enough to stop these deceptive practices.

We would propose, at a minimum that the following measures should be taken:

- FDA should be working closely with FTC to monitor and control such claims on labels and in advertising and promotional literature.
- There should be a clearing house established under the aegis of the FDA to assess what is known and what is not known about various supplement products and make this information available to consumers on a continuing basis, including updates on adverse reactions and unsupportable claims.

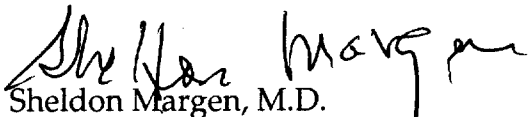
The widespread use of untested "nutritional supplements" for prevention and treatment purposes is, in effect a gigantic social experiment, being conducted on unknowing participants who do not have enough information available to them to consent to such testing. Although research is starting to be carried out on a relatively small scale, the funding is simply not available to keep up with the growth

99N-1174

T813

of the industry. The supplement manufacturers seem unwilling (and probably unable) to fund large clinical trials because, unlike the pharmaceutical industry, they will not ultimately be able to patent their formulations. The government, which is well positioned to administer such research, does not have the available funds to conduct it without help from the industry. But the door has been opened wide and we can not and must not wait for the present state of affairs to result in another thalidomide disaster before we insist that these products meet some standards for safety and efficacy. To this end, we further recommend:

- Legislation that would provide for a tax on manufacturers, based on a percentage of gross receipts from the sale of dietary supplements. The resulting fund would be used by FDA and NIH to finance the desperately needed clinical studies.

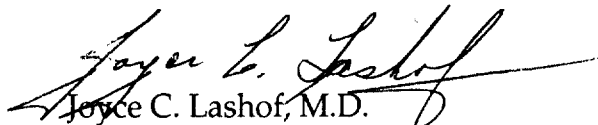


Sheldon Margen, M.D.

Professor Emeritus

School of Public Health,

Chair, Editorial Board, UC Berkeley Wellness Letter



Joyce C. Lashof, M.D.

Professor and Dean Emerita

School of Public Health

Associate Chair, Editorial Board, UC Berkeley Wellness Letter